Controversies in Coronary Revascularization

Atlanta CCU
April 15, 2016

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Disclosures

Grant Support

- Medtronic, PI SHEAR STENT Trial
- Abbott Vascular, PI Restoration Study (Subanalysis of ABSORB III Img.)
- Gilead, PI MARINA Trial Giliead
- Volcano Therapeutics, Research Grants and Steering Comm ADVISE II
- St. Jude Medical, Research Grants and Steering Comm ILUMIEN III
- American Heart Association, Mentor Fellowship Awards
- National Institute of Health, Co-I NIH ROI/PPG
- American College of Cardiology, Deputy Editor, JACC Interventions
Controversies in Coronary Revascularization

• SIHD
  - Accepted Indications for revascularization
  - Controversies in revascularization
    - How much Ischemia to Revascularize
    - How to revascularize 3 VD: CABG vs PCI vs HCR
    - How to revascularize LMCA: CABG vs PCI

• ACS
  - Accepted Indications for revascularization
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    - Non culprit vessel in STEMI: PCI vs Med tx.
    - Culprit vessel in STEMI: Angio vs OCT guided
Clinical Presentation

Stable angina

STEMI

CCS Class IV

Severity of Angina

ASx, CCS Class I

High risk

Ischemia Tests/Prognostic Factors

None, Low risk

Max

Medical Therapy

None

Anatomic Disease

LM + 3v CAD

* CHF, DM, Low LVEF

Appropriateness Criteria: Key Variables

Patel, et al. JACC 2009; 53:530-553

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Courage Trial

N=2287 pt
Stable angina

Survival Benefit with Revascularization
Stratified by Ischemic Risk

N=10 627 undergoing MPI with 1.9 ±0.6 year f/u propensity matched.

Hachamovitch et al Circulation. 2003; 107:2900-2907
SPECT MPI Does Not Localize Regional Ischemia in Severe Multivessel Disease

N=143 pts, with severe 3 VD who underwent Gated SPECT with 1 month

Lima..Samady JACC, 2003;42:64-70

Complexity of Angiographic Lesion Assessment

Kern and Samady. JACC 2010;55:173-185
Fractional Flow Reserve

Validation of FFR For Intermediate Lesion Assessment

<table>
<thead>
<tr>
<th>Index</th>
<th>Author (Ref. #)</th>
<th>n</th>
<th>Ischemic Test</th>
<th>BCV</th>
<th>Accuracy</th>
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<td>FFR</td>
<td>Pijls et al. (2)</td>
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<td>Abe et al. (28)</td>
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<td>DeBruyne et al. (35)</td>
<td>57</td>
<td>MIIBI-SPECT/post-MI</td>
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<td>Samady et al. (36)</td>
<td>48</td>
<td>MIIBI-SPECT/post-MI</td>
<td>0.78</td>
<td>85</td>
</tr>
</tbody>
</table>

Kern and Samady. JACC 2010;55:173-185
**FAME 2: FFR-Guided PCI versus Medical Therapy in Stable CAD**

Stable CAD patients scheduled for 1, 2 or 3 vessel DES-PCI  
N = 1220

- **Randomized Trial**: FFR in all target lesions
- **Registry**: 50% randomly assigned to FU

Follow-up after 1, 6 months, 1, 2, 3, 4, and 5 years

**Primary Outcomes**

- **PCI+MT vs. MT**: HR 0.32 (0.19-0.53); p<0.001
- **PCI+MT vs. Registry**: HR 1.29 (0.49-3.39); p=0.61
- **MT vs. Registry**: HR 4.32 (1.75-10.7); p<0.001

<table>
<thead>
<tr>
<th>Months after randomization</th>
<th>MT</th>
<th>PCI+MT</th>
<th>Registry</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>447</td>
<td>447</td>
<td>166</td>
</tr>
<tr>
<td>1</td>
<td>414</td>
<td>414</td>
<td>156</td>
</tr>
<tr>
<td>2</td>
<td>370</td>
<td>388</td>
<td>145</td>
</tr>
<tr>
<td>3</td>
<td>322</td>
<td>351</td>
<td>133</td>
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<tr>
<td>4</td>
<td>283</td>
<td>308</td>
<td>117</td>
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<tr>
<td>5</td>
<td>253</td>
<td>277</td>
<td>106</td>
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<td>6</td>
<td>220</td>
<td>243</td>
<td>93</td>
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<td>7</td>
<td>192</td>
<td>212</td>
<td>74</td>
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<td>8</td>
<td>162</td>
<td>175</td>
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<td>9</td>
<td>127</td>
<td>155</td>
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<tr>
<td>10</td>
<td>100</td>
<td>117</td>
<td>41</td>
</tr>
<tr>
<td>11</td>
<td>70</td>
<td>92</td>
<td>25</td>
</tr>
<tr>
<td>12</td>
<td>37</td>
<td>53</td>
<td>13</td>
</tr>
</tbody>
</table>

Cumulative incidence (%)
Relationship Between FFR and Outcomes

FAME 2: Patients with angiographically significant stenoses treated with OMT

Event Rates (%)

0 2 4 6 8 10 12 14 16 18

FFR > 0.90 0.81-0.90 0.71-0.80 0.61-0.70 0.51-0.60 <0.50

Stenosis Severity (FFR)

Courtesy of: Bernard De Bruyne, MD, PhD

ISCHEMIA Overview

International Study of Comparative Health Effectiveness with Medical and Invasive Approaches

Chair - Judith Hochman, Co-Chair/PI - David Maron
Co-PIs William Boden, Bruce Ferguson, Robert Harrington, Gregg Stone, David Williams

- **Patients**: stable, at least moderate ischemia (core lab)
- **Primary Aim**: to determine whether an initial invasive strategy of cath and revascularization (PCI or CABG) + OMT is superior to a conservative strategy of OMT alone, with cath reserved for OMT failure
- **Composite Primary Endpoint**: CV death or MI
- **Major Secondary Endpoint**: angina-related QOL
- **Sample Size**: 8,000
- **Follow-up**: average ~4 years

ISCHEMIA

Oct 2014
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HCR Clinical Significance

- Combines IMA graft to LAD & PCI to non-LAD targets for multi-vessel CAD that includes proximal LAD (or LM) & ≥ 1 other vessel

- Presumed to optimize outcomes by combining
  - Durability and benefit of surgical LIMA to LAD
  - Minimal invasiveness of PCI
  - Avoid morbidity and late SVG failure of multi-vessel CABG
  - Minimize repeat revascularization, esp LAD
Risk-Adjusted MACCE-Free Survival Analysis

HCR (n=200) | PCI (n=98)
---|---

<table>
<thead>
<tr>
<th>MACCE Free Survival (Months)</th>
<th>HCR</th>
<th>PCI w/ DES</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.99</td>
<td>0.99</td>
</tr>
<tr>
<td>5</td>
<td>0.98</td>
<td>0.95</td>
</tr>
<tr>
<td>10</td>
<td>0.96</td>
<td>0.90</td>
</tr>
<tr>
<td>15</td>
<td>0.94</td>
<td>0.85</td>
</tr>
<tr>
<td>20</td>
<td>0.92</td>
<td>0.80</td>
</tr>
<tr>
<td>25</td>
<td>0.90</td>
<td>0.75</td>
</tr>
</tbody>
</table>

FAME Study: One Year Outcomes

- **Angio-Guided**
  - Death: 3%
  - MI: 8.7%
  - Repeat Revasc: 9.5%
  - MACE: 18.3%

- **FFR-Guided**
  - Death: 1.8%
  - MI: 5.7%
  - Repeat Revasc: 6.5%
  - MACE: 13.2%

- **Statistical Significance**
  - Death/MI: p=0.04
  - MACE: p=0.02
MACE in SYNTAX – 3VD and FAME

![Graph showing MACE in SYNTAX and FAME](image)

Functional SYNTAX Score:

![Graph showing Functional SYNTAX Score](image)

Functional SYNTAX Score:

FAME 3

- 1500 pts with multivessel CAD
- Considered candidates for CABG + PCI
- Randomized to FFR guided PCI vs CABG
- Non-inferiority trial design
- Primary: One Year follow-up for Death, MI, CVA, Revascularization
- Key Secondary: Three Year follow-up for Death/MI/CVA
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No Adverse Events with Deferred CABG for FFR≥0.80

N=213 patients with 30-70% Left main stenosis

Hamilos. Circulation 2009;120:1505-1512
### PCI vs. CABG for Left Main Disease
#### Meta-analysis of 4 RCTs, 1,611 Patients

**1 Year Mortality**

<table>
<thead>
<tr>
<th></th>
<th>PCI</th>
<th>CABG</th>
<th>OR (95%CI)</th>
<th>p-Value</th>
<th>OR (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEMANS</td>
<td>1/52</td>
<td>4/53</td>
<td>0.24 (0.03-2.23)</td>
<td>0.21</td>
<td></td>
</tr>
<tr>
<td>SYNTAX left main</td>
<td>15/355</td>
<td>15/336</td>
<td>0.94 (0.45-1.96)</td>
<td>0.88</td>
<td></td>
</tr>
<tr>
<td>Boudriot et al.</td>
<td>2/100</td>
<td>5/101</td>
<td>0.39 (0.07-2.07)</td>
<td>0.27</td>
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</tr>
<tr>
<td>PRECOMBAT</td>
<td>6/300</td>
<td>8/300</td>
<td>0.75 (0.26-2.17)</td>
<td>0.59</td>
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<tr>
<td>Fixed effects estimate</td>
<td>3.0% (24/807)</td>
<td>4.1% (32/790)</td>
<td>0.74 (0.43-1.28)</td>
<td>0.29</td>
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</tr>
<tr>
<td>Random effects estimate</td>
<td></td>
<td></td>
<td>0.74 (0.43-1.28)</td>
<td>0.29</td>
<td></td>
</tr>
</tbody>
</table>

\( I^2 = 0\% \)

**Favors PCI**

**Favors CABG**

*Capodanno et al, JACC 2011;58:1426-32*

---

### PCI vs. CABG for Left Main Disease
#### Meta-analysis of 4 RCTs, 1,611 Patients

**1 Year Myocardial Infarction**

<table>
<thead>
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<th>CABG</th>
<th>OR (95%CI)</th>
<th>p-Value</th>
<th>OR (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEMANS</td>
<td>1/52</td>
<td>3/53</td>
<td>0.33 (0.03-3.25)</td>
<td>0.34</td>
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</tr>
<tr>
<td>SYNTAX left main</td>
<td>15/355</td>
<td>14/336</td>
<td>1.02 (0.48-2.14)</td>
<td>0.97</td>
<td></td>
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<tr>
<td>Boudriot et al.</td>
<td>3/100</td>
<td>3/101</td>
<td>1.01 (0.20-5.13)</td>
<td>0.99</td>
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<tr>
<td>PRECOMBAT</td>
<td>4/300</td>
<td>3/300</td>
<td>1.34 (0.30-6.03)</td>
<td>0.71</td>
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</tr>
<tr>
<td>Fixed effects estimate</td>
<td>2.8% (23/807)</td>
<td>2.9% (23/790)</td>
<td>0.98 (0.54-1.78)</td>
<td>0.95</td>
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<tr>
<td>Random effects estimate</td>
<td></td>
<td></td>
<td>0.98 (0.54-1.78)</td>
<td>0.95</td>
<td></td>
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\( I^2 = 0\% \)

**Favors PCI**

**Favors CABG**

*Capodanno et al, JACC 2011;58:1426-32*
PCI vs. CABG for Left Main Disease
Meta-analysis of 4 RCTs, 1,611 Patients

1 Year Stroke

<table>
<thead>
<tr>
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<th>PCI</th>
<th>CABG</th>
<th>OR (95% CI)</th>
<th>p-Value</th>
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</thead>
<tbody>
<tr>
<td>LEMANS</td>
<td>0/52</td>
<td>2/53</td>
<td>0.20 (0.01-4.09)</td>
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<tr>
<td>SYNTAX left main</td>
<td>1/355</td>
<td>8/336</td>
<td>0.12 (0.01-0.93)</td>
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<td>Boudriot et al.</td>
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<td>0/300</td>
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<td>1.7%</td>
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<td>0.0 (0.03-0.67)</td>
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I²=0%

Capodanno et al, JACC 2011;58:1426-32

PCI vs. CABG for Left Main Disease
Meta-analysis of 4 RCTs, 1,611 Patients

1 Year MACCE

Capodanno et al, JACC 2011;58:1426-32
Patient Profiling in LM Revascularization

Local Heart team (surgeon & interventional cardiologist) assessed each patient in regards to:

- Patient’s operative risk
- Coronary lesion complexity (SYNTAX score)
- Goal: SYNTAX score to provide

Valjimigle et al, Am J Cardiol 2007;99:1072–1081
Unprotected left main coronary artery disease – patients with low and mid tertile SYNTAX scores potentially suitable for both PCI and CABG

UPLM PCI to Improve Survival (ACS)

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ila—For UA/NSTEMI if not a CABG candidate</td>
<td>B</td>
</tr>
<tr>
<td>Ila—For STEMI when distal coronary flow is &lt;TIMI grade 3 and PCI can be performed more rapidly and safely than CABG</td>
<td>C</td>
</tr>
</tbody>
</table>
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AUC 2012: At the Bedside

Patel, et al. JACC 2009; 53:530-553
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Case 1: FFR for Assessment Of Non-Culprit Lesions in STEMI

• 68 yr old male, HTN, DM, high chol, with 2 hours of severe substernal chest pain and inferior ST segment elevations

• Brought emergently to the cath lab. 
AUC 2012: At the Bedside

N=101 patients undergoing PCI for AMI
(75 STEMI and 26 N-STEMI)
N= 112 lesions

FFR of non-culprit lesions was measured at time of culprit vessel PCI and repeated 35+4 days later

In a subgroup of 14 patients, IMR was also measured at time of culprit vessel PCI and repeated 35+4 days later

Ntalianis et al. JACC Int. Volume 3, Issue 12, December 2010, Pages 1274-1281
### FFR in Non-Culprit Bed Acute Setting

<table>
<thead>
<tr>
<th></th>
<th>Acute Phase (n = 101)</th>
<th>Follow-Up (n = 101)</th>
<th>p Value</th>
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</thead>
<tbody>
<tr>
<td>LVEF (%)</td>
<td>59 ± 15</td>
<td>61 ± 14</td>
<td>NS</td>
</tr>
<tr>
<td>LVEDP (mm Hg)</td>
<td>18 ± 7</td>
<td>17 ± 7</td>
<td>NS</td>
</tr>
<tr>
<td>DS nonculprit (%)</td>
<td>56 ± 14</td>
<td>55 ± 14</td>
<td>NS</td>
</tr>
<tr>
<td>MLD nonculprit (mm)</td>
<td>1.32 ± 0.46</td>
<td>1.31 ± 0.50</td>
<td>NS</td>
</tr>
<tr>
<td>RD nonculprit (mm)</td>
<td>2.9 ± 0.70</td>
<td>2.7 ± 0.70</td>
<td>NS</td>
</tr>
<tr>
<td>TIMI flow nonculprit</td>
<td>2.93 ± 0.30</td>
<td>2.97 ± 0.20</td>
<td>NS</td>
</tr>
<tr>
<td>cTFC nonculprit</td>
<td>15 ± 6</td>
<td>15 ± 6</td>
<td>NS</td>
</tr>
</tbody>
</table>

*Values are mean ± SD.*

FFR = fractional flow reserve; IMR = index of microcirculatory resistance; LVEDP = left ventricular end-diastolic pressure; LVEF = left ventricular ejection fraction; MLD = minimum lumen diameter; RD = reference diameter.

Ntalaniás et al. JACC Int. Volume 3, Issue 12, December 2010, Pages 1274-1281

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### Preventative Angioplasty in MI

#### 450 pts with STEMI MVD, 5 UK Centers

HR was 0.35
For composite and each individual endpoint

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Position of MLA in relation to Plaque Rupture

...not necessarily coincident: prox or distal

[Image of Plaque Rupture, MLA site, and Proximal Reference]

Courtesy of Dr. Giulio Guagliumi
**OCT for Identification of Culprit Lesion Morphology**

Plaque Rupture

![Plaque Rupture Image](image)

Plaque Erosion

![Plaque Erosion Image](image)

*Courtesy of Dr. Giulio Guagliumi*

---

**Plaque Erosion in STEMI patients Tx with DAPT Only**

![Table 2](image)

*Table 2: Procedural Characteristics*

<table>
<thead>
<tr>
<th></th>
<th>Group 1 (n = 12)</th>
<th>Group 2 (n = 19)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycoprotein IIb/IIIa inhibitors</td>
<td>4 (33)</td>
<td>4 (21)</td>
<td>0.73</td>
</tr>
<tr>
<td>ADP antagonists</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>7 (58)</td>
<td>18 (95)</td>
<td>0.012</td>
</tr>
<tr>
<td>Prasugrel</td>
<td>5 (42)</td>
<td>1 (5)</td>
<td></td>
</tr>
<tr>
<td>Angiographic analysis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-aspiration DS, %</td>
<td>79.4 ± 33.3</td>
<td>67.9 ± 17.3</td>
<td>0.05</td>
</tr>
<tr>
<td>Post-aspiration DS, %</td>
<td>27.1 ± 19.4</td>
<td>32.0 ± 35.2</td>
<td>0.48</td>
</tr>
<tr>
<td>Pre-aspiration TIMI flow grade ≤2</td>
<td>9 (75)</td>
<td>15 (79)</td>
<td>0.85</td>
</tr>
<tr>
<td>Post-aspiration TIMI flow grade &lt;2</td>
<td>1 (8)</td>
<td>0</td>
<td>0.81</td>
</tr>
<tr>
<td>Total ischemic time, h</td>
<td>3.5 ± 3.0</td>
<td>2.8 ± 2.3</td>
<td>0.82</td>
</tr>
</tbody>
</table>

At 753 days follow up all patients were asymptomatic

*Prati et al. JACC CV Img, Vol 6, No 3, 2013*
Controversies in Coronary Revascularization

• **SIHD**
  - Accepted Indications for revascularization
  - Controversies in revascularization
    - How much Ischemia to Revascularize
    - How to revascularize 3 VD: CABG vs PCI vs HCR
    - How to revascularize LMCA: CABG vs PCI

• **ACS**
  - Accepted Indications for revascularization
  - Controversies in revascularization
    - Non culprit vessel in STEMI: PCI vs Med tx.
    - Culprit vessel in STEMI: Angio vs OCT guided

Atlanta CCU
April 15, 2016

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